

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER-OF PATENTS AND TRADEMARKS  
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

06/497,422 03/02/10 BERRY

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EXAMINER

ELIZABETH R.

ART UNIT PAPER NUMBER

1615

DATE MAILED:

08/31/01

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/497,422             | BERRY ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Blessing M. Fubara     | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_ .
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-42 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____                                    |

#### DETAILED ACTION

Examiner acknowledges receipt of paper number 14 filed 06/26/01.

1. The finality of the last office action is withdrawn. The amendment filed 04/02/01 is entered. The pending claims are 1 and 3-42. Amended claims 1, 3-8, 12, 14, 15, 29, 30, new claims 39-42 and original claims 9-11, 13, 16-28 and 31-38 are examined.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 3-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 14, 15, 39-42 recite “type” and the term type is indefinite. See Ex parte Copenhaver, POBA, 1955, 109 USPQ 118-119.

Claim 10 recites “surfactant is gml” and “gml” is indefinite. The abbreviation “gml” appears to refer to or represent glycerol manolaurate. See page 12, line 17 of the disclosure. Applicants may overcome this rejection by replacing the abbreviation “gml” with glycerol manolaurate if that is applicants’ invention.

Claims 1.3,4, 15, 30-32, 41 and 42 are confusing. Applicants argue that the invention is directed to non-aqueous single phase viscous vehicles. However, claims 1, 3, 4, 15, 31, 41 and 42 permit suspension and claim 30 permits dispersion.

A clarification is required because the designated claims appear to have suspensions/dispersions that represent multiphase compositions. Do applicants permit a single phase prior to introduction of beneficial agent?

In the rejections that follow, assumption is made that the invention permits suspension because claims 1, 3, 4, 15, 31, 41 and 42 permit suspension and claim 30 permits dispersion.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-7, 12-14, 19, 20, 24, 25, 26, 33, 39-42 rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (US 5,374, 620).

Clark discloses a growth-promoting composition. The composition comprises liquid carriers or finely divided solid carriers (column 12, lines 13 and 14). The carriers are non-aqueous vehicles (column 12, lines 20-22). The carrier contains minor amounts of ascorbic acid, low molecular weight polypeptides, proteins, polyvinylpyrrolidone, glycine, amino acids, carbohydrates, sugar alcohols and polysorbates or poloxamers or PEG (column 12, lines 24-41). In one embodiment, the composition comprises polypropylene glycol or glycerol (column 13, lines 16-18). In example 1, Clark teaches that the pump employed to deliver the composition can be implanted to continuously deliver the composition. The teaching of Clark encompass the scope of the claims. The mode of delivery of a composition and what the composition does is not critical in a composition claim.

Art Unit: 1615

6. Claims 1, 3-7, 12-14, 19,20, 24, 25, 26, 33, 39-42 rejected under 35 U.S.C. 102(b) as being anticipated by Sparks et al. (US 4,952,402).

Sparks discloses a liquid composition that can be formulated into tablets. The liquid composition comprises controlled release powder of discrete micro-particles (column 1, lines 38-43). In one embodiment the composition comprises a solution of polymer or polymers in a solvent, active ingredient dissolved or dispersed in the polymer solution (column 1, lines 44-53). In another embodiment, the composition is a controlled release antibiotic formulation in the form of powders, non-aqueous suspension of powders or reconstituted aqueous suspensions of powders (column 1, lines 55-61). The polymer could be a synthetic polymer such as polyvinylpyrrolidone (column 3, lines 15-35). Nutritional supplement such as ascorbic acid or tocopherol may be present in the composition (column 4, lines 51-53). The invention may be used as implants or ocular inserts (column 7, lines 63 and 64). A specific example comprises theophylline active ingredient, polymer, vegetable oil, glycerin and polysorbate (column 6, lines 38-54 and column 15, lines 20-25). The teachings of Sparks meet the limitations of the claims.

Applicants claim a broad composition comprising active ingredient, surfactant, polymer and a solvent. Although applicants claim a viscous vehicle, the generic claims do not recite any viscosity values. The claims are confusing because while applicants claim single-phase viscous vehicle, the claims also allow for multiphase vehicles by permitting suspensions and dispersions. The comprising language of the generic claims does not exclude other ingredients.

***Claim Objections***

7. Claims 30-32 are objected to because of the following informalities: Claim 33 depends from claims 41 or 42. A preceding claim can not depend from a subsequent claim. Appropriate correction is required.

8. Observation:

The clause "wherein the components are not of the same type" occurs twice in claim 39.

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
August 23, 2001

TK  
THURMAN K. PAGE  
SUPERIOR PATENT EXAMINER  
ART UNIT 1615